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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,738	09/22/2003	EmadEldin M. Hassan	Hassan2001A	1894

110 7590 10/20/2004

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/667,738

**Applicant(s)**

HASSAN, EMADELDIN M.

**Examiner**

Chih-Min Kam

**Art Unit**

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 26-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 26-45 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.                                                |

### **DETAILED ACTION**

1. In the preliminary amendment filed September 23, 2003, claims 1-25 have been cancelled, and new claims 26-45 have been added. Therefore, claims 26-45 are pending.

#### ***Election/Restrictions***

2. Restriction to one of the following inventions is required under 35 U. S. C. 121:

- I. Claims 26-30, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an antidiabetic agent such as insulin, comprising dissolving the material in a first liquid component of an emulsion system to form a solution, adding to the solution a second component of an emulsion system and an emulsifier to form a mixture and applying force to the mixture to transform the mixture into an emulsion, and treating the emulsion with an additional amount of a liquid miscible with the first and second components, and transforming the emulsion into a liquid-solid suspension, and the solid phase comprises nanoparticles of the material, classified in class 424, subclass 489, and class 530, subclass 303.

- II. Claims 26-28 and 31, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an immunosuppressant such as cyclosporin, classified in class 424, subclass 489, and class 514, subclass 9.

- III. Claims 26-28 and 32, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an anticancer agent such as paclitaxel, classified in class 424, subclass 489, and class 514, subclass 449.

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IV. Claims 26-28 and 33, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an antifungal agent such as nystatin, classified in class 424, subclass 489, and class 514, subclass 449.

V. Claims 26-28 and 34, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an antiviral agent such as acyclovir, ribarivan and interferons, classified in class 424, subclass 489, and class 514, subclass 2.

VI. Claims 26-28 and 35, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an antibacterial agent such as penicillin, cephalosporin..... and metronidazole, classified in class 424, subclass 489, and class 514, subclass 199.

VII. Claims 26-28, 36 and 37, in part, drawn to a method for making nanoparticles of a substantially water insoluble material, which is an anti-HIV drug such as a HIV protease inhibitor, classified in class 424, subclass 489, and class 514, subclass 220.

VIII. Claims 38-40, in part, drawn to a method for making nanoparticles of a substantially water insoluble material comprising a diagnostic agent such as an iodopamide derivative as a light imaging contrast material for x-ray imaging, classified in class 424, subclasses 489 and 9.4.

IX. Claims 38, 39, 41 and 42, in part, drawn to a method for making nanoparticles of a substantially water insoluble material comprising a diagnostic agent such as a metal oxide as nuclear resonance imaging contrast material, classified in class 424, subclasses 489 and 646.

X. Claims 38, 39 and 43, in part, drawn to a method for making nanoparticles of a substantially water insoluble material comprising a diagnostic agent such as a radio-labeled

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Technetium oxide as a marker for diagnostic nuclear medicine used in scintigraphy, classified in class 424, subclasses 489 and 1.11.

XI. Claims 44-45, drawn to a method for making nanoparticles of a substantially water insoluble material selected from the group consisting of pigment, photographing material, cosmetic ingredient, support material and toner material, classified in class 424, subclasses 489 and 401.

Should Group XI be elected, applicant is required to elect one type of insoluble material from pigment, photographing material, cosmetic ingredient, support material, and toner material. Each type of insoluble material, which has different structure and utility, is patentably distinct. This is not species election.

2. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I-XI are distinct from each other because they use different insoluble materials which are structurally and functionally entities, and produce different nanoparticles which have different utilities.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent subject matter, and because inventions I-XI require different searches but are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached at 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Patent Examiner



CMK  
October 16, 2004